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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,869	01/10/2002	James A. Shayman	30275/38157	9824

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EXAMINER	
COPPINS, JANET L	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,869	SHAYMAN, JAMES A.	
	Examiner	Art Unit	
	Janet Coppins	1625	

-- Th MAILING DATE of this communication appears on the cov r she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-31 pending in the instant application.

Receipt is acknowledged of Applicants' Amendment to Correct Inventorship, which has been reviewed, and changes have been made of record in the file.

Information Disclosure Statement

Receipt is acknowledged of Applicant's Information Disclosure Statement, which papers have been reviewed by the Examiner and entered of record in the file as Paper No. 5.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6, 8, 9, 11, 18, 20-23, 26, and 28-31 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not give any guidance as to the full range of diabetic complicating diseases which could be treated or prevented using the instant claimed process. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,

7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(a) In the instant Claims 8, 20, and 28, Applicants are claiming a method of treating microbial or viral infections. The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant specification does not give any guidance as to the full range of microbial or viral infections that could be treated using the instant claimed process. In order to practice the claimed invention, one skilled in the art would have to speculate which microbial or viral infection could be treated or prevented using the amino ceramide-like compounds found in the instant claims. Further, the phrase "microbial" encompasses infections caused by not only bacteria, but fungi and yeast, none of which has been specified. The number of possible microbial or viral infections embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the broad terminology "A method for treating a patient having a microbial or viral infection" is not enabled because the metes and bounds of the infections which could be treated or prevented using the amino ceramide-like compounds found in the instant claims cannot be ascertained.

(b) Claims 6, 9-11, 18, 21-23, 26, and 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating all tumors or cancers. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described, as mentioned supra. For example, the cancer therapy art remains highly unpredictable. Presently over 3000 different types of specific cancers exist. The various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

(c) Claims 6, 18, and 26 recite in line 1, "A method for inhibiting the growth of cancer cells in a mammal...," yet the specification fails to describe either specific cell lines or certain cancer types.

(d) Claims 9, 21, and 29 recite the phrase, "A method for treating a patient having a drug resistant tumor..." however this is based on a disclosure which is not enabling (see In re Wands, 8 USPQ2d 1400, 1988), because the Applicants do not indicate in the disclosure that the instant claimed compounds are superior to all other anti-cancer prodrugs. Sufficient evidence is lacking which would show a quantitative advantage over all other compounds that are known to have therapeutic uses for treating malignant tumors. The lack of evidentiary data prevents one of ordinary skill in the art from accepting any therapeutic regimen on its face, especially above other known prodrugs.

(e) Claims 11, 23, and 31 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure that is not enabling. The recited "vaccination method," critical or essential to the

practice of the invention, but not included in the claims, is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The attenuating toxin has not been identified for vaccination, and more than routine experimentation is required to arrive at the invention (vaccination method) as intended by the Applicants. In addition, the method of "removing cancer cells" of step a) has not been described in the disclosure and in step b), the cancer cells are merely treated *in vitro*. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any vaccine or immunization treatment or any therapeutic regimen on its face. In order to provide proof of utility with regard to drugs and their uses, either clinical *in vivo* or *in vitro* data correlative to *in vivo* applicability or a combination of these can be used. However, the data must be such as to convince one of ordinary skill in the art that the proposed utility is sufficiently established as set forth in full, clear and exact terms in the disclosure. When the utility is directed to humans, the data must generally be clinical, and no such data has been provided in the instant application.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-17, 19, 20-24, and 27-31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1, 12, and 24 all define the term R_3 as a tertiary amine, but fail to describe the amine and specify whether the amine moiety is aliphatic or heterocyclic.

(b) Claims 1, and 12 recite the phrase "...R_4 is a group that is selectively hydrolyzed in a target cell," however it is unclear what moiety is being hydrolyzed, and the functional language fails to indicate what target cell is doing the hydrolyzation. One of ordinary skill in the art would assume that typically enzymes play the role of hydrolyzing, and the "target cell" produces said enzymes, however the intent of the inventor is unclear in the instant claims.

(c) Claims 3, 14, and 15 all recite the phrase "...wherein n is at least 1..." yet fail to set an upper limit for the value of n.

(d) Claim 24 fails to define the invention properly, because the value of the variable n has not been described.

(e) Claims 8, 20, and 28 recite the phrase "A method for treating a patient having a microbial or viral infection..." however this functional language is vague because microbial infections consist of bacterial, fungal, or yeast-causing infections, and it is unclear what kind of infection the Applicants are intending to treat.

(f) Claims 9, 21, and 29 all recite "A method for treating a patient having a drug resistant tumor..." yet it is unclear what type of tumor or cancer is being treated.

(g) Claims 10, 22, and 30 all recite "A method for reducing tumor angiogenesis..." in line 1 yet fails to specify the type of tumor.

(h) Claims 11, 23, and 31 recite in step a) the phrase, "removing cancer cells..." which is vague and indefinite because it is unclear how the Applicants are intending to remove the cells (i.e. *in vivo* or via surgery) and from what location (i.e. organ, marrow, blood, etc) and whether the cancer has metastasized.

4. Claims 2, 4, 5, 7, 13, 16, 17, 19, and 27 rejected under 35 U.S.C. 112, second paragraph, as being dependent on base claims that stand rejected under 35 U.S.C. 112, second paragraph.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 12, 13, 24, 25 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 4 of U.S. Patent No. 6,030,995. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed formula of Claims 12 and 13, when R_4 is H, is the same as the compound of Claim 1 of the '995 patent when R_1 is a hydroxy-, methoxy-, etc substituted phenyl group. In addition, the instant claimed compounds of Claim 24 and 25 are the same as the compounds claimed in the '995 patent, when R_1 of the reference is a substituted phenyl group.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Coppins whose telephone number is 703.308.4422. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703.308.4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703.746.9037 for regular communications and 703.872.9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1235.

Janet L. Coppins
February 10, 2003

Alan L. Rotman

ALAN L. ROTMAN
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